

16080347

5. 510(k) Summary

OCT - 9 2008

510(k) Summary

as required by section 807.92(c)

Identification: UNISCAN-DoA system

1. USDoA-01: UNISCAN-DoA Scanner
2. SUDoA-01: mAMP/Opi/THC panel test

Description: The UNISCAN-DoA system includes UNISCAN-DoA scanner and mAMP/Opi/THC panel test.

The UNISCAN-DoA scanner is a scientific measurement device for color intensity of developed test strip. The color intensity of a test line is detected by the contact image sensor (CIS) inside the device.

The test strip of UNISCAN-DoA system is a one-step, colloidal gold based chromatographic immunoassay for the rapid, qualitative detection of Methamphetamine, Opiates, and THC (Cannabinoid).

Proprietary and Established Names:

UNISCANTM-DoA system
UNISCAN-DoA Scanner
mAMP/Opi/THC Panel test

Name of Manufacturer:

Taiwan Unison Biotech Inc. (TUBI)
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Contact Person:

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Intended Use: This mAMP/Opi/THC panel test is a prescription assay intended for use with UNISCAN-DoA scanner in laboratory by professional personnel. The mAMP/Opi/THC assays were calibrated with

d-methamphetamine/morphine/11-nor- Δ^9 -THC-9-COOH, respectively. It provides qualitative screening results for Methamphetamine/Opiate/cannabinoids in human urine at a cutoff concentration of 1000/300/50 ng/ml. For In Vitro Diagnostic Use.

This assay provides only a preliminary result. Clinical consideration and professional judgment should be applied to any Drug of Abuse test result, particularly in evaluating a preliminary positive result. To obtain a confirmed analytical result, a more specific alternate chemical method is needed. Gas Chromatography/Mass Spectroscopy (GC/MS) is the recommended confirmatory method.

Technology: UNISCAN-DoA system, like multi-drug tests from other manufacturer such as Roche, American Biotech Inc, and Forefront Diagnostic Inc, etc., detects the presence of target drugs or their metabolites by one step, chromatographic, and competitive immunoassay technology. Currently marketed Triage TOX Drug Screen (whose 510(k) number is K043242) is used for substantial equivalence predicate kit. All of these products are based on the same immunochemical principle of recognition and formation of specific antibody / target drug / antibody / complexes.

The device contains a membrane strip, which is pre-coated with drug-protein conjugate at the test region of the membrane strip. A wicking pad containing anti-drug monoclonal antibody-conjugate is placed at one end of the membrane. The device contains a control region which has a different antigen/antibody from the test region.

The assay relies on the competition for binding antibody between drug conjugate and free drug that may be present in the urine specimen being tested. When drug is present in the urine specimen, it competes with drug conjugate for limited amount of antibody-colloidal gold conjugate. If the drug is present in the urine specimen, it will prevent the binding of drug conjugate to the antibody. Therefore, the color intensity of the test line is reduced. The higher the drug concentration is present in the urine specimen, the lower the color intensity is in the test line of a strip. The color intensity of a test line is inversely proportional to the drug concentration in the urine specimen. The correlation between the color intensity and the drug concentration is described by a calibration curve, whose coefficients are determined via nonlinear regression based on the experimental data. The calibration curve equation and its coefficients are stored in UNISCAN-DoA scanner. Once a developed test strip is inserted into the

scanner and is scanned by the device, the color intensity of a test line is detected by the contact image sensor (CIS) inside the device and the signal is converted to drug concentration according to the stored calibration curve equation and its coefficients. The qualitative result is then displayed on the LCD screen of the device.

A control line is present at the control region to work as procedural control. This colored band should always appear at the control region regardless the presence of drugs or metabolite. The UNISCAN-DoA scanner automatically detects the color intensity of a control line. If the control line of an inserted test strip does not be detected by the device, “Strip is Failed!” will be displayed on the LCD screen of the device.

Performance: The product performance characteristics of UNISCAN-DoA system was evaluated in studies. The results of these studies demonstrated that UNISCAN-DoA system can be performed by professional and laboratory personnel to obtain a qualitative and rapid detection of drugs of abuse.

a. **mAMP:** 97 urine specimens were used to evaluate the performance of mAMP assay.

UNISCAN Results	Less than half the cutoff concentration by GC/MS analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Positive	0	2	5	42
Negative	43	4	1	0

% Agreement among positives is 97.9% (47/48)

% Agreement among negatives is 95.9% (47/49)

b. **Opi:** 94 urine specimens were used to evaluate the performance of Opi assay.

UNISCAN Results	Less than half the cutoff concentration by GC/MS analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Positive	0	0	3	41
Negative	43	5	2	0

% Agreement among positives is 95.7% (44/46)

% Agreement among negatives is 100% (48/48)

c. THC: 94 urine specimens were used to evaluate the performance of THC assay.

UNISCAN Results	Less than half the cutoff concentration by GC/MS analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Positive	0	1	4	41
Negative	43	4	1	0

% Agreement among positives is 97.8% (45/46)

% Agreement among negatives is 97.9% (47/48)

Conclusion: Both subject and predicate device Triage TOX Drug Screen (whose 510(k) number is K043242) are qualitative immunochromatographic single-use tests for measurement of the same analyte(s) in the same matrix. Both subject and predicate devices are competitive immunoassays.

The studies demonstrate the substantial equivalence of Uniscan-DoA system to existing products already marketed for screening drugs of abuse. The safety and effectiveness of the subject are established and it is appropriate for commercial distribution.



Food and Drug Administration
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Hsinchu, (Taiwan) China

OCT -9 2008

Re: k080347

Trade/Device Name: mAmp/Opi/THC Panel Test with SUDoA-01 Scanner
Regulation Number: 21 CFR 862.3610
Regulation Name: Methamphetamine Test System.
Regulatory Class: Class II
Product Codes: DJC, DJG, LDJ
Dated: September 23, 2008
Received: September 25, 2008

Dear Tzu-Wei Li:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.

Director

Division of Chemistry and Toxicology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

4. Indication for Use Statement

Indication for Use

510(k) Number (if known): K 080347

Device Name: UNISCAN-DoA system

1. USDoA-01: UNISCAN-DoA Scanner

2. SUDoA-01: mAMP/Opi/THC panel test

Indication for Use:

TUBI's UNISCAN-DoA is a system intended for use in Drugs of Abuse Screening Tests.

This mAMP/Opi/THC panel test is a prescription assay intended for use with UNISCAN-DoA scanner in laboratory by professional personnel. The mAMP/Opi/THC assays were calibrated with d-methamphetamine/morphine/11-nor- Δ^9 -THC-9-COOH, respectively. It provides qualitative screening results for Methamphetamine/ Opiate/cannabinoids in human urine at a cutoff concentration of 1000/300/50 ng/ml. For In Vitro Diagnostic Use.

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Prescription Use ✓
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use _____
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)



Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K 080347